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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
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|-----------------|-------------|----------------------|---------------------|

09/084,837 05/26/98 LUTTICKEN

H I/97269-US

EXAMINER

HM22/0313

AKZO NOBEL N V  
1300 PICCARD DRIVE SUITE 206  
ROCKVILLE MD 20850-4373

ART UNIT PAPER NUMBER

1648  
DATE MAILED:

03/13/01

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

# Office Action Summary

Application No.

09/084,837

Applicant(s)

Lutticken et al

Examiner

Mary Mosher

Group Art Unit

1648



☒ Responsive to communication(s) filed on 12/13/00

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire three month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

## Disposition of Claim

☒ Claim(s) 32-39 is/are pending in the application.

Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

☐ Claim(s) \_\_\_\_\_ is/are allowed.

☒ Claim(s) 32-39 is/are rejected.

☐ Claim(s) \_\_\_\_\_ is/are objected to.

☐ Claims \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some\* ☒ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

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## **DETAILED ACTION**

### ***Claim Rejections - 35 USC § 103***

Claims 32-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over the lost interference count, optionally in view of any or all of Lewin, Culver et al, Roizman, DeWind et al, and Keeler, for the same reasons as the previous rejection of claims 33-39. The previous Office action contained a typographical error, and should have been directed to claims 32-29.

Applicant argues that the prior art does not provide motivation to introduce more than one mutation in the VP5 gene, since the Mundt reference taught that a single mutation was sufficient to obtain attenuation, and there was no suggestion that reversion was a problem. The examiner agrees that neither the count nor the Mundt reference specifies a non-reverting mutation which comprises the substitution of at least two nucleotides of the start codon. However, the examiner maintains that reversion of single point mutations was a well-known phenomenon, and that loss of attenuation was also a well-known problem in the art of live viral vaccines. Therefore, it is maintained that one of ordinary skill would not require particular direction or specific teachings of instability, to be motivated to choose a method of inactivating the VP5 gene which has a low probability of reversion to a non-attenuated form. Such inactivation methods include known methods of altering more than one nucleotide in the start codon and adding multi-frame stop codons. The 1.132 declaration by Dr. Mundt has been considered, but the observed lack of reversion is seen as the expected result, not an unexpected result. Therefore, the arguments are unconvincing, and the rejection is maintained.

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*Conclusion*

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary E. Mosher, Ph.D. whose telephone number is (703) 308-2926. The examiner can normally be reached on Monday -Thursday and alternate Fridays from 6:30 AM to 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached on (703) 308-4027. The fax phone number for this Group is now (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

March 9, 2001

  
**MARY E. MOSHER**  
**PRIMARY EXAMINER**  
**GROUP 1800**  
1600